

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 3

Complete if Known

Application Number	10/626,943
Filing Date	July 25, 2003
First Named Inventor	Rubino
Group Art Unit	1614
Examiner Name	G. Polansky
Attorney Docket Number	AM-100802

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

FOREIGN PATENT DOCUMENTS

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	1	WO-94/02136	02-03-1994	Smithkline Beecham Corp.		
	2	WO-00/33878	06-15-2000	Novartis		
	3	WO-98/30205	07-16-1998	Sonus Pharma. Inc.		
	4	WO-99/45918	09-16-1999	Naphro Biotherapeutics, Inc.		

Examiner Signature

Date
Considered

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This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 USC 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETE FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**

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OTHER PRIOR ART-NONPATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item, (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue, number(s), publisher, city and/or country where published	T ²	
	5	FIEDLER, H. <i>Lexikon der Hilfsstoffe für Pharmazie, Kosmetik und angrenzende Gebiete</i> , vol. 2, no. 4, Auglage, pp. 1210-1217, Cantor-Verlag, Aulendorf, Deutschland, 1996.		
	6	PODSYPANINA, K., An inhibitor of mTOR reduces neoplasia and normalizes p70/S6 kinase activity in Pten ^{+/+} mice, PNAS, vol. 98, no. 18, pp. 10320-10325, August 2001.		
	7	SWEETANA, S. AND AKERS, M., Solubility principles and practices for parenteral drug dosage form development, PDA Journal of Pharmaceutical Science and Technology, vol. 50, no. 5, pp. 330-342, September 1996.		
	8	STRICKLEY, R., Parenteral formulations of small molecules therapeutics marketed in the United States (1999) Part I, Journal of Pharmaceutical Science and Technology, vol. 53, no. 6, pp. 324-349, November 1999.		
	9	POWELL, M., Compendium of Excipients for Parenteral Formulations, PDA Journal of Pharmaceutical Science and Technology, vol. 52, no. 5, pp. 238-311, November 1999.		
	10	SORBERA, L.A., et al, CCI-779 Oncolytic mTOR inhibitor, Drugs of the Future, vol. 27, no. 1, pp. 7-13, January 2002.		
	11	Wyeth Pharmaceuticals Inc, HIGHLIGHTS OF PRESCRIBING INFORMATION, (Torisel, temsirolimus), Philadelphia, USA, May 2007.		
	12	GARBER, K., Rapamycin's Resurrection: A new way to target the cancer cell cycle, J. National Cancer Institute, vol. 93, no. 20, pp. 1517-1519, October 2001.		
	13	GRUNWALD, V., et al, Inhibitors of mTOR reverse doxorubicin resistance conferred by PTEN status in prostate cancer cells, Cancer Research, vol. 62, pp. 6141-6145, November 2002.		
	14	DUDKIN, Biochemical correlates of mTOR inhibition by the rapamycin ester CCI-779 and tumor growth inhibition, Clinical Cancer Research, vol. 7, pp. 1758-1764, June 2001.		
	15	GEORGER, Antitumor activity of the rapamycin analog CCI-779 in human primitive neuroectodermal tumor/medulloblastoma models as single agent and in combination therapy, Cancer Research, vol. 61, pp. 1527-1532, February 2001.		
	16	"Solution Formulations" in Pharmaceutical Preformulation and Formulation, 2001, pp. 196-210.		

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